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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,645	02/10/2005	Claude Prigent	50376/004001	7358

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	**PAPER NUMBER**
1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,645	PRIGENT ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 14-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 14-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 and 14-25 are all the pending claims for this application and subject to lack of unity restriction and election of species requirement.

Lack of Unity Restriction

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is an anti- human or murine aurora-A kinase monoclonal antibody that does not inhibit the enzymatic activity of the kinase, can be fixed on membranes expressing the protein, allows detection of the protein and stains tissues. In view of this, Cremet et al. (Mol. and Cell. Biochem. 243:123-131 (January 2003); cited in the IDS of 12/10/04) disclose the technical feature, and therefore, the claims are not linked to form a single inventive concept. Cremet discloses generation of a Mab, 35C1, which recognizes both human and mouse aurora-A kinase (Figure 4), does not inhibit aurora-A kinase activity (Figure 6), identified spindle poles protein in human and mouse cells by immunostaining (Figure 4B) and immunoprecipitates the protein from human and mouse cells (Figure 4A). Therefore the technical feature recited in claims 1 and 14-25 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 14, 20 and 22, drawn to an anti-aurora-A kinase Mab recognizing both the human and mouse protein, the 35C1 Mab, a kit comprising the Mab, and a pharmaceutical composition.

Group II, claim(s) 15-19, drawn to a method for in vitro diagnosis or prognosis of cancers in humans or animals comprising the anti-aurora-A kinase Mab.

Group III, claim 21, drawn to a method for treating cancer comprising the anti-aurora-A kinase Mab.

Group IV, claim(s) 23 and 24, drawn to a method for screening inhibitors of aurora-A kinase comprising the anti-aurora-A kinase Mab.

Group V, claim(s) 25, drawn to a method for the preparation of the anti-aurora-A kinase Mab.

4. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Cremet et al. the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claims 1and 14-25 is not special.

The inventions of Groups I-V are separate and distinct as follows:

5. The antibody of Group I is not required to practice the methods of Groups II-IV because the method of diagnosing or prognosing cancer in vitro (Group II) can be practiced with a materially different reagent such as an enzyme assay for aurora-A kinase; the method of treating a cancer (Group III) can be practiced with a materially

different reagent such as chemotherapy, small molecule drugs, radiotherapy, etc.; and the method of screening inhibitors of aurora-A kinase can be practiced with materially different reagent such as NF-kappaB (Sun et al., Biochem Biophys Res Commun. 2007 Jan 5;352(1):220-5).

6. The methods of Groups II-V require different method steps, different reagents used, and have different intended populations. The method of Group II requires diagnosing or prognosing a cancer whereas none of Groups II-VI requires these steps or intended population as an endpoint. The method of Group III requires treating cancer whereas none of Groups II, IV and V requires these steps or intended population as an endpoint. The method of Group IV requires screening for inhibitors of aurora A kinase whereas none of Groups II, III and V requires these steps or intended population as an endpoint. And the method of Group V requires generating a monoclonal antibody for aurora A kinase whereas none of Groups II-IV requires these steps, use of a aurora A kinase protein or the intended population as an endpoint.

7. The antibody of Group I and the method of producing the antibody of Group V are related as product and process of making, but the antibody can be made by a materially different process such as phage display followed by subcloning of the selected binding fragments into antibody constant regions to generate specific, monoclonal antibodies.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species Requirement

10. If Group II or III is elected, then species (cancer) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie 1) breast cancers

Specie 2) colorectal cancers

Specie 3) stomach cancers

In the instant case the species of cancer can originate from any number of different cell types (e.g., epithelial, mesothelial or endothelial). Also, the cancers being

associated with different organs are under the influence of different growth factors, hormones, cytokines, etc. Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate tissues and organs. This suggests that any method inventions involving administering a diagnostic or therapeutic in the realm of a cancer, would require different routes of administration, dosing, formulation, sensitivity of detection, etc., and that one could not predict biodistribution of the diagnostic or therapeutic agent in a subject much less an outcome of success for diagnosing or treating all breast, colorectal or stomach cancers in following the same method steps or conditions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 15 (Group II) and Claim 21 (Group III) are generic as to species 1-3.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER